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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/567,055	03/06/2006	Federico Stroppolo	1446002	4891

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EXAMINER

NGUYEN, THUKHANH T

ART UNIT	PAPER NUMBER
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1791

MAIL DATE	DELIVERY MODE
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07/01/2009

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/567,055	Applicant(s) STROPPOLO ET AL.	
	Examiner THU KHANH T. NGUYEN	Art Unit 1791	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 13 April 2009.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-3 and 5-20 is/are pending in the application.
- 4a) Of the above claim(s) 9-19 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-3, 5-8 and 20 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input checked="" type="checkbox"/> Other: <u>JP 09193149; WO 00/10801</u> |

DETAILED ACTION

Claim Rejections - 35 USC § 103

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

2. Claims 1-3, 5-8 and 20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Holderbaum et al (WO 00/10801), or Kubo et al (WO03/037589) or the US equivalent 7,208,113, or Kato et al (6,227,836) in view of Ueno (JP 09193149).

Holderbaum et al disclose a tablet pressing apparatus, comprising stamping punch (2) having an adhesion-reducing coating comprising PTFE (see abstract).

Kato et al disclose a tablets manufacturing apparatus, comprising a plurality of upper punches (16, 17) each having a releasing coating formed by the sprayers (13a-b) or a layer of powder –intercepting films (125), wherein the coating material includes polytetrafluoroethylene (col. 8, lines 33-39).

Kubo et al disclose a tablet forming machine having a rotary die plate (1) having a plurality of dies (2), a plurality of upper (13) and lower punches (10), wherein the punches (10, 13) are provided with a release agent layer (col. 2, lines 32-36).

However, these references fail to disclose that the coating layer having a thickness of 0.01 microns and 10 nm.

Ueno discloses a tablet forming apparatus, comprising a coating layer on the surface of the punch with a thickness of 0.5-50 microns.

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One of ordinary skilled in the art would have been motivated to provide Holderbaum, Kato, or Kubo with a coating layer having appropriate thickness depending on the type of material being mold, the material of the punches and the pressing condition, such as a coating having a thickness of 0.5-50 microns as taught by Ueno in order to prevent pressing material from sticking to the punch while prevent the coating layer from quick wear and tear. In *Gardner v. TEC Systems, Inc.*, 725 F.2d 1338, 220 USPQ 777 (Fed. Cir. 1984), cert. denied, 469 U.S. 830, 225 USPQ 232 (1984), the Federal Circuit held that, where the only difference between the prior art and the claims was a recitation of relative dimensions of the claimed device and a device having the claimed relative dimensions would not perform differently than the prior art device, the claimed device was not patentably distinct from the prior art device.

In regard to claims 2-3 and 6-7, wherein the release agent layer in Kubo contains fluorine-base release agent (col. 2, lines 42-44) such as polytetrafluoroethylene (col. 2, lines 46-48).

In regard to claims 4, 8 and 20, wherein Kubo further discloses that the release agent layer/coating has a thickness of 0.001 μ m to 0.07 μ m.

Response to Arguments

3. Applicant's arguments filed April 13, 2009 have been fully considered but they are not persuasive. The Applicant alleged that Kubo's spray-coating system would cause a problem for tablet forming. However, as described in Kato, spray-coating system is also widely used in pharmaceutical tablets forming. Further, this is the intended use, which cannot used to determine the patentability of apparatus claims. A claim containing a "recitation with respect to the manner

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in which a claimed apparatus is intended to be employed does not differentiate the claimed apparatus from a prior art apparatus” if the prior art apparatus teaches all the structural limitations of the claim. *Ex parte Masham, 2 USPQ2d 1647 (Bd. Pat. App. & Inter. 1987)*.

4. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to THU KHANH T. NGUYEN whose telephone number is (571) 272-1136. The examiner can normally be reached on 6:30am-4:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yogendra Gupta can be reached on 571-272-1316. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Yogendra N Gupta/
Supervisory Patent Examiner, Art Unit 1791

TN